purposes of providing a complete reply to the Action, Applicants affirm the election of Group I (Claims 1-43) for prosecution.

Claims 1-18 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,302,844 to Walker et al. (Walker) in view of U.S. Patent No. 6,161,095 to Brown (Brown) and Applicants' alleged admission in the background of the invention of the present application. Claims 19-28 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Walker in view of Brown, Applicants' alleged admission in the background of the invention of the present application, and U.S. Patent No, 6,024,699 to Surwit et al. (Surwit). Claims 29-43 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Walker in view of Brown.

Applicants have amended Claims 1-6, 8, 10-20, 22-24, 27-35 and 37-43 as indicated above to further clarify the nature of Applicants' invention. Attached hereto is a marked-up version of the changes made to the claims. The attachment is captioned "Version with Markings to Show Changes Made."

Rejections Under 35 U.S.C. § 103

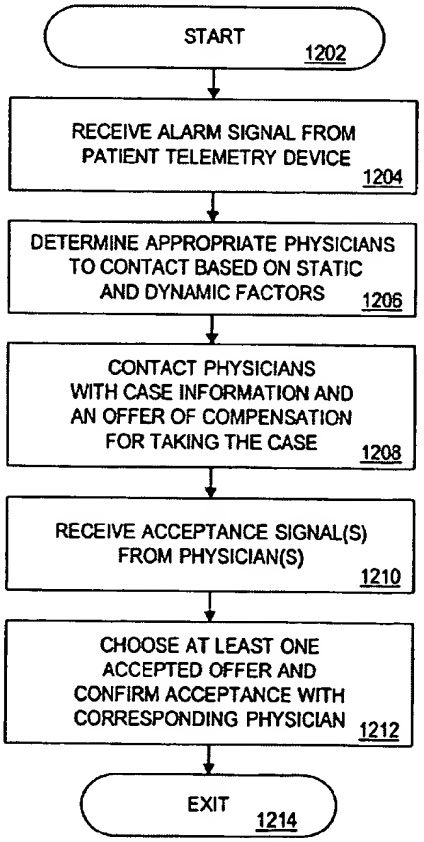
To establish a prima facie case of obviousness, the prior art reference, or references when combined, must teach or suggest ***all*** the recitations of the claims, and there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. M.P.E.P. § 2143. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also ***suggests the desirability*** of the combination. M.P.E.P. § 2143.01, citing *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990).

As recently emphasized by the Court of Appeals for the Federal Circuit, to support combining references, evidence of a suggestion, teaching, or motivation to combine must be ***clear and particular***, and this requirement for clear and particular evidence is not met by broad and conclusory statements about the teachings of references. *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). In an even more recent decision, the Court of Appeals for the Federal Circuit has stated that, to support combining or modifying references, there must be particular evidence from the prior art as to the ***reason*** the skilled artisan, with

no knowledge of the claimed invention, **would have selected these components for combination in the manner claimed**. *In re Kotzab*, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000).

Walker

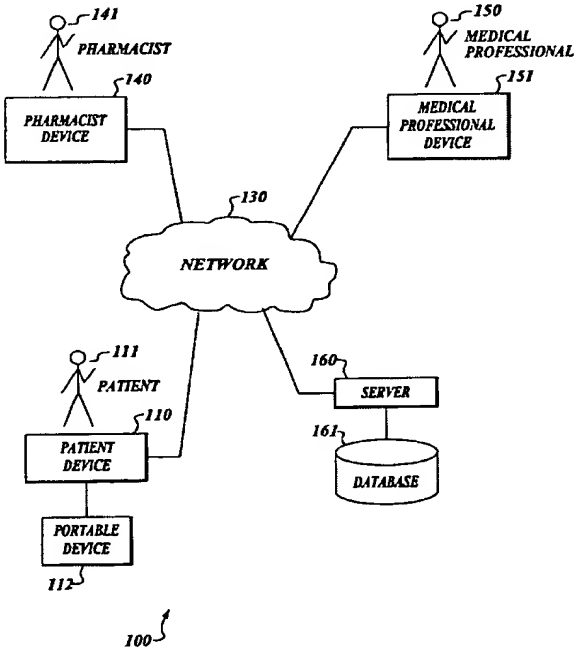
Walker describes a system and method for obtaining medical care wherein patient information is sent to one or more physicians with an offer of compensation for taking the case. An "accept" or "decline" signal is received from one or more physicians and a physician is selected from a pool of "accept signals". The Walker system and method provides (a) an initial screening and decision capability based upon the received operating data sufficient to determine which type of expert is needed; (b) an identification and communication of at least a portion of the operating data to one or more appropriate experts; (c) a transactional capability defining a level of compensation to be provided to the expert in exchange for the rendering of an expert diagnosis regarding the anomaly; and (d) an adaptation of an existing communications infrastructure to the procurement of the expert opinion(s). (Walker, Co. 3, Lines 17-27). Fig. 11 from Walker is set forth below:



Brown

Brown describes a method and system for interaction with a community of individuals, relating to compliance with and effectiveness of treatment regimens, including supply and use of pharmaceuticals, using a protocol or other intelligent message which acts in place of a service provider and which is capable of collecting or imparting information to patients in place thereof. Individuals interact with the protocol or intelligent message to provide assistance in all aspects of treatment regimen compliance, data collection, supply or delivery, review and modification. These aspects can include (1) reminders regarding compliance with a selected treatment regimen for medication, physical therapy, psychological therapy, self-improvement, or some combination thereof, (2) data collection of facts regarding patient compliance, symptomology, possible drug interactions or side effects of medication if required by the treatment regimen, and other facts relevant to evaluation and possible modification of the treatment regimen; (3) networked integration with workstations for medical professionals to automate approvals and modifications, and refills and delivery of medication if required by the treatment regimen. (Brown, Col. 2, Line 53 - Col. 3, Line 6).

Fig. 1 of Brown is illustrated below:



The Brown system 100 monitors compliance with a treatment regimen using a protocol or other intelligent message which acts in place of a service provider to collect and impart

information relevant to the treatment regimen, including a patient device 110, a pharmacist device 140, a medical professional device 150, and a server device 160. The devices are coupled using a communication network 130, and a portable device 112 which can be coupled to the patient device 110 to receive information regarding the treatment regimen and send feedback from the patient 111 responsive thereto. The portable device 112 of Brown includes a coupling element 113 for coupling the portable device 112 to the patient device 110, a memory element 114, a processor chip 115 including a clock circuit 116, a presentation element 117, and a patient feedback input element 118.

A service provider determines a treatment regimen for selected patients 111 and a protocol to be followed by their portable devices 112 to assist the patients 111 in following the treatment regimen. The service provider sends the treatment regimen and protocol to the server device 160 where it is recorded in the database 161. The server device 160 sends the treatment regimen and protocol information to the patient device 110, and optionally to the pharmacist device 140 and the medical professional device 150.

The portable device 112 is coupled to the patient device 110 using the coupling element 113. While coupled, the treatment regimen and protocol information received by the patient device 110 is sent to the portable device 112 and recorded in the memory 114. After the treatment regimen and protocol information is recorded in the memory 114, the portable device 112 can be uncoupled from the patient device 110 and taken with the patient 110 to locations relatively or logically remote from the patient device 110. When the patient 111 is due to perform an act according to the treatment regimen, the portable device 112 uses the presentation element 117 to provide a reminder message instructing the patient 111 to perform that act. The patient 111 performs the indicated act and enters a message into the portable device 112 confirming performance of the act using the patient feedback input element 118. Operation of the patient feedback input element 118 causes the processor chip 115 to cancel the reminder message, check the clock 116, and record the time and fact of performance in the memory 114.

Obviousness Rejections Overcome:

Applicants' independent Claim 1 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Walker in view of Brown and Applicants' alleged admission in the

background of the invention of the present application. Claim 1 recites a method of monitoring anticoagulation therapy of a patient comprising the following steps ***performed by a portable apparatus***:

> receiving data from a patient ***at a portable apparatus*** ...;
> assessing severity of the received patient data ***via the portable apparatus***;
> ***prompting the patient to perform a patient-administered coagulation test if the received patient data are assessed to be above a threshold severity level via the portable apparatus***;
> ***receiving coagulation test results from the patient-administered test at the portable apparatus***; and
> ***communicating the received coagulation test results*** of the patient-administered test ***from the portable apparatus*** to a healthcare provider via a communications network.

Neither Walker nor Brown teaches or suggests a portable apparatus configured to perform all of the method steps of Claim 1. For example, neither Walker or Brown teaches or suggests a portable apparatus that ***assesses severity of data received from a patient***. Moreover, neither Walker or Brown teaches or suggests ***prompting the patient to perform a patient-administered coagulation test if the received patient data are assessed to be above a threshold severity level*** via the portable apparatus.

The Action, in fact, is silent with respect to the recited element of ***prompting the patient to perform a patient-administered coagulation test if the received patient data are assessed to be above a threshold severity level***. In lieu of this recited element, the Action states that Walker teaches "instructing the patient to take medication if the received results are not within an appropriate boundary, wherein if levels, for example blood glucose levels as measured and analyzed by the patient telemetry device, do not return to normal after a predetermined period of time, a physician or nurse is alerted." (Action , Pages 5-6). In that neither Walker nor Brown teach or suggest prompting a patient to perform a patient-administered coagulation test, Applicants respectfully fail to understand the relevance of the Action's argument that Walker teaches instructing a patient to take medicine.

Neither Walker nor Brown teaches or suggests a portable apparatus ***receiving coagulation test results from the patient-administered test***. In fact, the Action states that Walker teaches "receiving results from a patient ***at a central server***. (Action, Page 6). Moreover, the Action concedes that Walker "fails to expressly disclose the apparatus being

configured to receive and analyze information, specifically the information being related to patient compliance with patient-administered medication and test regimens, wherein the apparatus is configured to modify the patient-administered medication and test regimen." (Action, Page 6).

Because neither Walker or Brown teaches or suggests a portable apparatus that performs all of the recited elements of Claim 1 (e.g., assessing severity of received patient data; prompting a patient to perform a coagulation test if data is assessed to be above a threshold severity level; receiving coagulation test results from patient; communicating coagulation test results to a healthcare provider), Applicants respectfully submit that Claim 1, and all claims depending therefrom, are not rendered obvious. For at least the same reasons, independent Claims 10, 19, 29 and 37, and all claims depending therefrom, are also not rendered obvious by Walker and Brown, alone or in combination.

In addition, Claim 2 is independently patentable in that none of the cited references teaches or suggests a portable apparatus that assesses severity of received coagulation test results from a patient-administered coagulation test; that modifies a patient-administered medication regimen if the received coagulation test results from the patient-administered coagulation test are assessed to be above a threshold severity level; and that communicates the modified patient-administered medication regimen to the patient. For at least the same reason, Claims 11, 20, 30 and 38 are independently patentable.

Applicants respectfully request withdrawal of the present rejections under 35 U.S.C. §103.

It is not believed that an extension of time is required. In the event, however, that an extension of time is necessary, such an extension is hereby petitioned under 37 C.F.R. §1.136(a). Any additional fees believed to be due in connection herewith are hereby authorized to be charged to our Deposit Account No. 50-0220.

Conclusion

In view of the above, it is respectfully submitted that this application is in condition for allowance, which action is respectfully requested.

Respectfully submitted,

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20792

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Michele P. McMahan

Michele P. McMahan

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

The paragraph beginning at page 4, line 25 has been amended as follows:

In addition to case managers, AVMs, and home diagnostic devices, several systems have been devised that collect disease-related data at home and transmit them to a central location where the data can be analyzed by a physician or other healthcare professionals. Such systems include [DiabCare] DIABCARE (Roche Diagnostics), [The Buddy System] THE BUDDY SYSTEM, [Health Hero] HEALTH HERO, and [LifeChart] LIFECHART. Some of these systems directly interface with home physiologic monitors (e.g., [DiabCare] DIABCARE and [LifeChart] LIFECHART) as described above. However, all of these systems simply collect data from remotely-located patients and present the data in summary form. They do not attempt to help the physician or health care provider prioritize patients in need of attention, recommend actions to ameliorate the patient's condition, or give information back to the patient about what he or she should do in the event the a change in the therapy regimen in indicated.

The paragraph beginning at page 5, line 13 has been amended as follows:

One system that has attempted to automate disease management for insulin therapy in diabetes mellitus is the [Diacare] DIACARE® System, described in U.S. Patent No. 4,731,726. Unfortunately, the [Diacare] DIACARE® System is narrowly focused on treating diabetic patients using insulin, and lacks many of the important features of a system that would be necessary for delivering a wide variety of interventions in a number of medical diseases or conditions such as anticoagulation therapy.

The paragraph beginning at page 8, line 13 has been amended as follows:

According to one embodiment of the present invention, anticoagulation therapy is indicated for such diseases such as atrial fibrillation, deep venous thrombosis, and thrombosis secondary to prosthetic heart value replacement. Other medical diseases or conditions that can be managed using these methods include seizure disorders, attention deficit hyperactivity disorder, cancer therapies and palliative treatments, pain control, renal dysfunction, various forms of depression including manic depression, high blood pressure, asthma, physical rehabilitation following injury, surgery or stroke, cardiovascular conditioning in cardiac rehabilitation, primary prevention and wellness promotion in at-risk groups, can all be monitored and prescriptively controlled via a remote and preferably portable apparatus. Typically, disease therapy (also referred to as chronic disease management) includes a medication regimen (e.g., warfarin for anticoagulation therapy, lithium or [Depakote] DEPAKOTE® (Divalproex Sodium, Abbott Labs) medication for manic depression, [Depakene] DEPAKENE® (valproic acid, Abbott Labs) or [Tegretol] TEGRETOL® (carbamazepine USP; Basel Pharmaceuticals) for seizure disorders, [Ritalin] RITALIN® (methylphenidate hydrochloride USP; CIBA Pharmaceuticals) for attention deficit hyperactivity disorder, or G-CSF (granulocyte colony stimulating factor) or erythropoietin (a hormone manufactured primarily in the kidneys which stimulates red blood cell production) for cancer chemotherapy patients, L-dopa therapy in Parkinson's Disease, and test regimens for monitoring the efficacy or toxicity of the medication dosing regimen. In rehabilitation and wellness promotion the prescription may include exercises and assessment could involve measurement of physical conditioning, range of motion, strength, endurance, rigidity, fine motor control, tremors, and the like. These can be monitored remotely and algorithmically adjusted using prescribed software routines. Exemplary test regimens for diseases include prothrombin time (PT) test for anticoagulation, white blood cell count in cancer chemotherapy patients, potassium or bicarbonate in patients with renal failure, blood pressure in hypertension, heart rate recovering in physical conditioning, depression rating scores or neuropsychological test performance in depression, and pain rating scales in chronic pain, for example. --

The paragraph beginning at page 29, line 1 has been amended as follows:

-- Preferably, a CMC **16** has an Intel® 80486 processor (or equivalent) with at least eight megabytes (8 MB) of RAM, and at least five megabytes (5 MB) of persistent computer storage for caching. Even more preferable is an Intel® Pentium® processor (or equivalent). However, it is to be understood that various processors may be utilized to carry out the present invention without being limited to those enumerated herein. Although a color display is preferable, a black and white display or standard broadcast or cable television monitor may be used. A CMC **16**, if an IBM®, or IBM-compatible personal computer, preferably utilizes either a [Windows] WINDOWS®3.1, [Windows] WINDOWS 95®, [Windows] WINDOWS NT®, [Unix] UNIX®, or OS/2® operating system. However, it is to be understood that a terminal not having computational capability, such as an IBM® 3270 terminal or a network computer (NC), or having limited computational capability, such as a network PC (Net PC) may be utilized in accordance with an embodiment of the present invention for accessing the Internet in a client capacity. --

The paragraph beginning at page 54, line 8 has been amended as follows:

-- A PPM, such as the PPM **20** illustrated in **Fig. 2**, and described in copending U.S. Patent Application Serial No. 09/042,048, filed on March 13, 1998, which is incorporated herein by reference in its entirety, when utilized to monitor disease therapy in accordance with this embodiment of the present invention is referred to as a [CoagCare] COAGCARE™ Patient Monitor (CPM). A CPM may include all the features of a PPM described above and also includes computer code that receives and stores patient data provided by a patient. A Palm Pilot, available from 3Com Corporation, Santa Clara, California, may be provided with various program code to implement aspects of the present invention. --

In the Claims:

Claims 1-6, 8, 10-20, 22-24, 27-35 and 37-43 have been amended as follows:

1. (Amended) A method of monitoring anticoagulation therapy of a patient, wherein the anticoagulation therapy includes a patient-administered medication regimen selected from the group consisting of warfarin and vitamin K antagonists, heparin and glucosaminoglycans, and direct thrombin inhibitors, and a patient-administered regimen for a coagulation test that monitors efficacy of the medication regimen, wherein the coagulation test is selected from the group consisting of prothrombin time (PT) test, partial thromboplastin time (PTT) test, activated clotting time (ACT) test, heparin assays, ecarin clotting time (ECT) test, and thrombin clotting time test, wherein the apparatus is configured to receive and analyze information regarding patient compliance with the patient-administered medication and coagulation test regimens, and wherein the apparatus is configured to modify the patient-administered medication and coagulation test regimens, the method comprising the following steps performed by a portable apparatus:

receiving data from a patient at a portable apparatus, wherein the patient data includes at least one of physiological data, pathophysiological data, biological data, psychological data, neuropsychological data, and behavioral data;

assessing severity of the received patient data via the portable apparatus;

prompting the patient to perform a patient-administered coagulation test, via the portable apparatus, if the received patient data are assessed to be above a threshold severity level;

receiving coagulation test results from the patient-administered test at the portable apparatus; and

communicating the received coagulation test results [from] of the patient-administered test from the portable apparatus to a healthcare provider via a communications network.

2. (Amended) The method according to Claim 1 further comprising the steps of:

assessing severity of the received coagulation test results from the patient-administered coagulation test via the portable apparatus;

modifying the patient-administered medication regimen via the portable apparatus if the received coagulation test results from the patient-administered coagulation test are assessed to be above a threshold severity level; and

communicating the modified patient-administered medication regimen to the patient.

3. (Amended) The method according to Claim 2 further comprising the step of communicating the modified patient-administered medication regimen from the portable apparatus to a healthcare provider via a communications network.

4. (Amended) The method according to Claim 2 further comprising the step of communicating the modified patient-administered medication regimen from the portable apparatus to a remotely located data processing system via a communications network.

5. (Amended) The method according to Claim 1 further comprising the step of receiving at the portable apparatus [from the patient] information from the patient about patient compliance with the patient-administered medication and coagulation test regimens during a preceding time period.

6. (Amended) The method according to Claim 1 further comprising the step of automatically communicating the received patient data from the portable apparatus to a healthcare provider via a communications network if patient data are assessed to be above a threshold severity level.

8. (Amended) The method according to Claim 4 further comprising the step of communicating information regarding medication dosage from the portable apparatus to the patient in response to determining that the patient did not comply with the medication regimen in the preceding time period.

10. (Amended) A [An] portable apparatus that monitors anticoagulation therapy of a patient, wherein the
anticoagulation therapy includes a patient-administered medication regimen selected from the group consisting of warfarin and vitamin K antagonists, heparin and glucosaminoglycans, and direct thrombin inhibitors, and a patient-administered regimen for a coagulation test that monitors efficacy of the medication regimen, wherein the coagulation test is selected from the group consisting of prothrombin time (PT) test, partial thromboplastin time (PTT) test, activated clotting time (ACT) test, heparin assays, ecarin clotting time (ECT) test, and thrombin clotting time test, comprising:

a processor;

a user interface in communication with the processor;

computer code executable by the processor that receives and stores data from a patient, wherein the patient data includes at least one of physiological data, pathophysiological data, biological data, psychological data, neuropsychological data, and behavioral data;

computer code executable by the processor that assesses severity of the received patient data;

computer code executable by the processor that prompts a patient via the user interface to perform a patient-administered coagulation test if the received patient data are assessed to be above a threshold severity level;

computer code executable by the processor that receives and stores coagulation test results from the patient-administered coagulation test;

computer code executable by the processor that communicates the received coagulation test results from the patient-administered coagulation test to a healthcare provider via a communications network.

11. (Amended) The portable apparatus according to Claim 10 further comprising:

computer code executable by the processor that assesses severity of the received coagulation test results from the patient-administered coagulation test; computer

code executable by the processor that modifies the patient-administered medication regimen if the received coagulation test results from the patient-administered coagulation test are assessed to be above a threshold severity level; and

computer code executable by the processor that communicates the modified patient-administered medication regimen to the patient.

12. (Amended) The portable apparatus according to Claim 11 further comprising computer code executable by the processor that communicates the modified patient-administered medication regimen to a healthcare provider via a communications network.

13. (Amended) The portable apparatus according to Claim 11 further comprising computer code executable by the processor that communicates the modified patient-administered medication regimen to a remotely located data processing system via a communications network.

14. (Amended) The portable apparatus according to Claim 10 further comprising computer code executable by the processor that receives and stores information from a patient about patient compliance with the patient-administered medication and coagulation test regimens during a preceding time period.

15. (Amended) The portable apparatus according to Claim 10 further comprising computer code executable by the processor that automatically communicates the received patient data to a healthcare provider via a communications network if patient data are assessed to be above a threshold severity level.

16. (Amended) The portable apparatus according to Claim 15 wherein the computer code that automatically communicates the received patient data to a healthcare provider comprises computer code that sends a paging signal to a healthcare provider.

17. (Amended) The portable apparatus according to Claim 13 further comprising computer code executable by the processor that communicates information regarding medication dosage to the patient in response to determining that the patient did not comply with the medication regimen in the preceding time period.

18. (Amended) The portable apparatus according to Claim 10 wherein the received patient data comprises at least one of information about hemorrhagic symptoms experienced by the patient and information about non-hemorrhagic symptoms experienced by the patient.

19. (Amended) A system that monitors anticoagulation therapy of a patient, wherein the anticoagulation therapy includes a patient-administered medication regimen selected from the group consisting of warfarin and vitamin K antagonists, heparin and glucosaminoglycans, and direct thrombin inhibitors, and a patient-administered regimen for a coagulation test that monitors efficacy of the medication regimen, wherein the coagulation test is selected from the group consisting of prothrombin time (PT) test, partial thromboplastin time (PTT) test, activated clotting time (ACT) test, heparin assays, ecarin clotting time (ECT) test, and thrombin clotting time test, wherein the system comprises:

a portable patient apparatus, comprising:

a processor;

a user interface in communication with the processor;

computer code executable by the processor that receives and stores data from a patient, wherein the patient data includes at least one of physiological data, pathophysiological data, biological data, psychological data, neuropsychological data, and behavioral data;

computer code executable by the processor that assesses severity of the received patient data;

computer code executable by the processor that prompts the patient via the user interface to perform a patient-administered coagulation test if the received patient data are assessed to be above a threshold severity level;

computer code executable by the processor that receives and stores coagulation test results from the patient-administered coagulation test; and

computer code executable by the processor that communicates the received coagulation test results from the patient-administered coagulation test to a healthcare provider via a communications network; and

a remotely located data processing system configured to communicate with and receive data from the portable patient apparatus, the remotely located data processing system comprising:

computer code that obtains patient data from the patient apparatus;

computer code that analyzes the obtained patient data from to identify medical conditions of a patient;

computer code that displays identified patient medical conditions for a patient in selectable, prioritized order according to medical severity via a remotely located client in communication with the central data processing system; and

computer code that displays treatment options for treating a selected medical condition for a patient.

20. (Amended) The system according to Claim 19 wherein the portable patient apparatus further comprises:

computer code executable by the processor that assesses severity of the received coagulation test results from the patient-administered coagulation test; computer code executable by the processor that modifies the patient-administered medication regimen if the received coagulation test results from the patient-administered coagulation test are assessed to be above a threshold severity level; and

computer code executable by the processor that communicates the modified patient-administered medication regimen to the patient.

22. (Amended) The system according to Claim 21 wherein the computer code that communicates treatment information from the remotely located data processing

system to the portable patient apparatus comprises computer code that transmits treatment information via wireless, satellite, telephone, e-mail, AVM or facsimile transmission.

23. (Amended) The system according to Claim 22 wherein the computer code that communicates treatment information from the remotely located data processing system to the portable patient apparatus comprises computer code that modifies the medication algorithm within the portable patient apparatus.

24. (Amended) The system according to Claim 19 wherein the computer code that obtains patient data from the portable patient apparatus further comprises:

computer code that analyzes data transmitted from the patient apparatus substantially simultaneously with the transmission thereof to the remotely located data processing system to identify emergency medical conditions requiring immediate medical attention; and

computer code that automatically communicates treatment information to the patient apparatus for an identified emergency medical condition.

27. (Amended) The system according to Claim 19 wherein the portable patient apparatus further comprises computer code that receives information via the user interface about patient compliance with the patient-administered medication regimen and the patient-administered coagulation test regimen during a preceding time period.

28. (Amended) The system according to Claim 19 wherein the portable patient apparatus further comprises computer code that communicates information regarding medication dosage to a patient via the user interface in response to determining that a patient did not comply with the patient-administered medication regimen in a preceding time period.

29. (Amended) A method of monitoring disease therapy of a patient via a portable patient apparatus, wherein the disease is selected from the group consisting of asthma, cancer chemotherapy, depression, high blood pressure, seizure disorders, and thrombosis, wherein the disease therapy includes a patient-administered medication regimen

and a patient-administered regimen for a test that monitors efficacy of the medication regimen, wherein the portable patient apparatus is configured to receive and analyze information regarding patient compliance with the patient-administered medication and test regimens, and wherein the portable patient apparatus is configured to modify the patient-administered medication and test regimens, the method comprising the following steps performed by the apparatus:

receiving data from a patient at a portable patient apparatus, wherein the patient data includes at least one of physiological data, pathophysiological data, biological data, psychological data, neuropsychological data, and behavioral data;

assessing severity of the received patient data via the portable patient apparatus;

prompting the patient to perform a patient-administered test if the received patient data are assessed to be above a threshold severity level via the portable patient apparatus;

receiving test results from the patient-administered test at the portable patient apparatus; and

communicating the received test results [from] of the patient-administered test from the portable patient apparatus to a healthcare provider via a communications network.

30. (Amended) The method according to Claim 29 further comprising the steps of:

assessing severity of the received test results from the patient-administered test via the portable patient apparatus;

modifying the patient-administered medication regimen via the portable patient apparatus if the received test results from the patient-administered test are assessed to be above a threshold severity level; and

communicating the modified patient-administered medication regimen to the patient.

31. (Amended) The method according to Claim 30 further

comprising the step of communicating the modified patient-administered medication regimen from the portable patient apparatus to a healthcare provider via a communications network.

32. (Amended) The method according to Claim 30 further comprising the step of communicating the modified patient-administered medication regimen from the portable patient apparatus to a remotely located data processing system via a communications network.

33. (Amended) The method according to Claim 29 further comprising the step of receiving at the portable patient apparatus [from the patient] information from the patient about patient compliance with the patient-administered medication and test regimens during a preceding time period.

34. (Amended) The method according to Claim 29 further comprising the step of automatically communicating the received patient data from the portable patient apparatus to a healthcare provider via a communications network if patient data are assessed to be above a threshold severity level.

35. (Amended) The method according to Claim 32 further comprising the step of communicating information regarding medication dosage from the portable patient apparatus to the patient in response to determining that the patient did not comply with the medication regimen in the preceding time period.

37. (Amended) A [An] portable apparatus that monitors disease therapy of a patient, wherein the disease is selected from the group consisting of asthma, cancer chemotherapy, depression, high blood pressure, seizure disorders, and thrombosis, wherein the disease therapy includes a patient-administered medication regimen and a patient-administered regimen for a test that monitors efficacy of the medication regimen, the portable apparatus comprising:

a processor;

a user interface in communication with the processor;

computer code executable by the processor that receives and stores data from a patient, wherein the patient data includes at least one of physiological data, pathophysiological data, biological data, psychological data, neuropsychological data, and behavioral data;

computer code executable by the processor that assesses severity of the received patient data;

computer code executable by the processor that prompts the patient via the user interface to perform a patient-administered test if the received patient data are assessed to be above a threshold severity level;

computer code executable by the processor that receives and stores test results from the patient-administered test; and

computer code executable by the processor that communicates the received test results from the patient-administered test to a healthcare provider via a communications network.

38. (Amended) The portable apparatus according to Claim 37 further comprising:

computer code executable by the processor that assesses severity of the received test results from the patient-administered test;

computer code executable by the processor that modifies the patient-administered medication regimen if the received test results from the patient-administered test are assessed to be above a threshold severity level; and

computer code executable by the processor that communicates the modified patient-administered medication regimen to the patient.

39. (Amended) The portable apparatus according to Claim 38 further comprising computer code executable by the processor that communicates the modified patient-administered medication regimen to a healthcare provider via a communications network.

40. (Amended) The portable apparatus according to Claim 38 further comprising computer code executable by the processor that communicates the modified patient-administered medication regimen to a remotely located data processing system via a communications network.

41. (Amended) The portable apparatus according to Claim 37 further comprising computer code executable by the processor that receives and stores information provided by the patient about patient compliance with the patient-administered medication and test regimens during a preceding time period.

42. (Amended) The portable apparatus according to Claim 37 further comprising computer code executable by the processor that automatically communicates the received patient data to a healthcare provider via a communications network if patient data are assessed to be above a threshold severity level.

43. (Amended) The portable apparatus according to Claim 40 further comprising computer code executable by the processor that communicates information regarding medication dosage to the patient in response to determining that the patient did not comply with the medication regimen in the preceding time period.